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Applicant: Borody, Thomas J., et al. Intl. Appl. No.: PCT/AU03/00257

> Serial No.: 10/506,728 Filed: September 3, 2004

Cust. No. : 20985
Title : ELECTROLYTE PURGATIVE

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : Unknown

Examiner: Unknown

Conf. No.: Unassigned

Dear Sir:

Transmitted herewith are an Information Disclosure Statement and Forms PTO-1449 (3 pages) and cited references for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first Office Action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman Reg. No. 33,779

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Stephanie L. Seidman

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INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§1.97-1.98

Dear Sir:

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application a fee is not required. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (2 pages) and copies of the cited references (excluding U.S. patents) are provided herewith in connection with the above-captioned application.

> CERTIFICATE OF MAILING BY "EXPRESS MAIL" "Express Mail" Mailing Label Number EV 399295451 Date of Deposit November 8, 2004

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Stephanie L. Seidman

Applicant: Thomas Juliu ody, et al.

Serial No.: 10/506,728
Filed: September 3, 2004
Information Disclosure Statement

Attorney ket No.: 17737-003US1/3703

The documents cited on the Form PTO-1449 are in the English language, with the exception of items noted below. Items, AV and AW (patent serial numbers RU 2098100 and JP 05306221, respectively) are in the Russian and Japanese language, and are supplied with English language Derwent abstracts (items BA and BB, respectively). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. 1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and make them of record in the file history of the above-captioned application.

Respectfully submitted,
Stephanie L. Seidman

Stephanie L. Seidbran Reg. No. 33,779

Attorney Docket No. 17737-003US1/3703US Address all correspondence to:

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San Diego, California 92130 Telephone: (858) 678-5070 Facsimile: (202) 626-7796

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Substitute Form PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 17737-003US1/3703US

September 3, 2004

Application No. 10/506,728

List of Patents and Publications for Applicant's Information Disclosure Statement

Applicant
Thomas Julius Borody, et al.

Group Art Unit
I Inknown

(37 CFR §1.98(b))

U.S. Patent Documents

Filing Date

Publication Examine Desig. Document Filing Date r Initial Number Patentee Class Subclass If Appropriate ID Date /A.H./ AA 20030180260 9/25/2003 Clancy et al. 424 934 5/9/2003 20040009961 1/15/2004 Borody 514 6/13/2003 AB 20040028689 2/12/2004 Borody 424 184.1 8/4/2003 AC. 20020035075 28 7/6/2001 3/21/2002 Borody 514 AD 30 7/31/2003 20040038329 2/26/2004 Clancy et al. 435 AE 7/12/1990 5196205 3/23/1993 Borody 424 653 AF 474 7/17/1990 5274001 12/28/1993 Borody 514 AG 5443826 8/22/1995 Borody 424 93 3 8/6/1993 AH 8/31/1992 5476669 12/19/1995 Borody 424 653 ΑĪ 5519014 5/21/1996 514 159 7/17/1994 Borody AJ 424 10/31/1996 5858403 1/12/1999 Borody et al. 456 AK 8/15/2000 6103268 8/15/2000 Borody et al. 424 489 ΑL 9/19/2000 Nishiyama et al. 9/4/1998 6121250 514 AM 6132767 10/17/2000 Borody et al. 424 456 10/17/2000 AN 6277836 159 11/17/1999 8/21/2001 Borody 514 AΩ 6426338 7/30/2002 Borody 514 159 12/17/1999 AP 6475518 2/1/2002 11/5/2002 Baumgart 424 451 ΑO 6489317 12/3/2002 11/20/2000 AR Borody 514 4/22/2003 424 780 7/6/2001 6551632 Borody AS 6645530 /A.H./ 11/11/2003 Borody 424 543 6/7/1995 AΤ

Foreign Patent Documents or Published Foreign Patent Applications								
Examine	Desig.	Document	Publication	Country or			Trans	lation
r Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
/A.H./	AU	EP0397689	11/22/1990	EP	A61K	04700		
∇	AV	EP0433299	6/26/1991	EP	A61K	03902		
/A.H./	AW	EP0439453	8/7/1991	EP	A61K	03324		

Examiner Signature

/Andriae Holt/

Date Considered

06/20/2008

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Applicant
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(37 CFR §1.98(b))

(Modified)

Substitute Form PTO-1449

Filing Date Group Art Unit
September 3, 2004 Unknown

Foreign Patent Documents or Published Foreign Patent Applications								
Examine	Desig.	Document	Publication	Country or		0.1.1		slation
r Initial /A.H./	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
77 111 13	AX	EP0554291	8/11/1993	EP	A61K	03160		
	AY	EP0771562	5/7/1997	EP	A61K	031185		
	AZ	JP 05306221	11/19/1993	Japan	A61K	31/19		X*
	BI	RU 2098100	12/10/1997	Russia	A61K	33/14		X*
	ВВ	WO0001378	1/13/2000	PCT	A61K	031015		
	BC	WO0180852	11/1/2001	PCT	A61K	031192		
	BD	WO0197821	12/27/2001	PCT	A61K	03574		
	BE	WO0203065	1/10/2002	PCT	G01N	03353		
	BF	WO0207741	1/31/2002	PCT	A61K	03574		
	BG	WO2003061767	7/31/2003	PCT	A61P	03104		
	ВН	WO2004070043	8/19/2004	PCT	C12N	0110		
	BJ	WO8501441	4/11/1985	PCT	A61K	35/78		
	BJ	WO8605981	10/23/1986	PCT	A61K	03129		
	BK	WO8903219	4/20/1989	PCT	A61K	03324		
	BL	WO8905659	6/29/1989	PCT	A61K	04700		
	ВМ	WO9001335	2/22/1990	PCT	A61K	03902		
	BN	WO9206690	4/30/1992	PCT	A61K	03160		
	во	WO9602236	2/1/1996	PCT	A61K	00920		
\Box	BP	WO9611014	4/18/1996	PCT	A61K	03574		
	BQ	WO9843667	10/8/1998	PCT	A61K	03904		
V	BR	WO9850043	11/12/1998	PCT	A61K	03160		
/A.H./	BS	WO9956749	11/11/1999	PCT	A61K	031445		

X*= An English Language Derwent Abstract is Provided

Other Documents (include Author, Title, Date, and Place of Publication)

Examine Desig.

r Initial ID Document

|A.H./| BT | Altomare DF, Memeo V, "Colonic explosion during diathermy colotomy. Report of a case", Diseases
| Colon Rectum Mar; 36(3):291-2 (1993) |
|A.H./| BU | Andrews PJ, Borody TJ, "Putting back the bugs': bacterial treatment relieves chronic constipation and symptoms of irritable bowle syndroms," Med J Aust. Nov 1, 159(9):633-4 (1993) |

	Examiner Signature /Andriae Holt/	Date Considered 06/20/2008	
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conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)

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Group Art Unit

(37 CFR §1.98(b))

Other Documents (include Author, Title, Date, and Place of Publication)

Filing Date

Examine	Desig.	
r Initial	ID	Document
/A.H./	BV	Arieff Al, Llach F, Massry SG, "Neurological manifestations and morbidity of hyponatremia: correlation with brain water and electrolytes", Medicine (Baltimore) Mar;55(2):121-9 (1976)
	BW	Borody TJ, "Flora Power' fecal bacteria cure chronic C. difficile diarrhea", Am J Gastroenterol. Nov;95(11):3028-9 (2000)
	вх	Borody TJ, "Helicobacter pylori eradication failure'salvage' therapies needed", <i>Ital J Gastroenterol Hepatol. Aug.</i> ; 30(4):375-7 (1998)
	BY	Borody TJ, Andrews P, Jankiewicz E, Ferch N, Carroll M, "Apparent reversal of early gastric mucosal atrophy after triple therapy for Helicobacter pylori", Am J Gastroenterol. Aug. 88(8):1266-68 (1993)
	BZ	Borody TJ, Ashman O., "Lactoferrin: milking ulcers?", Dig Liver Dis. Oct;35(10):691-3. (2003)
	CA	Borody TJ, Brandl S, Andrews P, Ferch N, Jankiewicz E, Hyland L, "Use of high efficacy, lower dose triple therapy to reduce side effects of eradicating Helicobacter pylori", Am J Gastroenterol. Jan. 89(1):33-8 (1994)
	СВ	Borody TJ, George L, Andrews P, Brandl S, Noonan S, Cole P, Hyland L, Morgan A, Maysey J, Moore-Jones D, "Bowel-flora alteration: a potential cure for inflammatory bowel disease and irritable bowel syndrome?", Med J Aust. May 15;150(10):604 (1989)
	СС	Borody TJ, George LL, Brandl S, Andrews P, Lenne J, Moore-Jones D, Devine M, Walton M, "Helicobacter pylori eradication with doxycycline-metronidazole-bismuth subcitrate triple therapy", Scand J Gastroenterol. Apr; 27(4):281-4 (1992)
	CD	Borody TJ, Shortis NP, Reyes E, "Eradication therapies for Helicobacter pylori", J Gastroenterol. 33 Suppl 10:53-6 (1998)
	CE	Borody TJ, Warren EF, Leis S, Surace R, Ashman O, "Treatment of ulcerative colitis using fecal bacteriotherapy", J Clin Gastroenterol. Jul; 37(1):42-7 (2003)
	CE	Borody TJ, Warren EF, Leis SM, Surace R, Ashman O, Siarakas S., "Bacteriotherapy using fecal flora: toying with human motions", J Clin Gastroenterol Jul;38(6):475-83 (2004)
	CG	Cohen CD, Keuneke C, Schiemann U, Schroppel B, Siegert S, Rascher W, Gross M, Schlondorff D, "Hyponatraemia as a complication of colonoscopy", Lancet Jan 27,357(9252):282-3 (2001)
	CD	de Boer WA, Borody TJ, "Treatment failures and secondary resistance to antibiotics. A growing concern in Helicobacter pylori therapy", Dig Liver Dis. Nov;32(8):673-5 (2000)
	CJ	Derwent Abstract Accession No. 93-408836, Class B05, JP 05306221 A (Horii Yakunhin Kogyo KK) 11/19/93 Abstract Only"
	CJ	Derwent Abstract Accession No. 98-375395, Class B05, RU 2098100 Cl (Maksimova et al.) 12/10/97 Abstract Only"
	СК	Fincher RK, Osgard EM, Jackson JL, Strong JS, Wong RK, "A comparison of bowel preparations for flexible sigmoidoscopy: oral magnesium citrate combined with oral bisacodyl, one hypertonic phosphate enema, or two hypertonic phosphate enemas", Am J Gastroenterol Aug;94(8):2122-7 (1999)
V	CL	Fraser CL, Kucharczyk J, Arieff Al, Rollin C, Sarnacki P, Norman D, "Sex differences result in increased morbidity from hyponatremia in female rats", Am J Physiol. Apr., 236(4 Pt 2):R880-5 (1989)
/A.H./	СМ	Melton JE, Patlak CS, Pettigrew KD, Cserr HF "Volume regulatory loss of Na, Cl, and K from rat brain during acute hyponatremia", Am J Physiol. Apr; 252(4 Pt 2):F661-9 (1987)

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